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Abstract

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The Efficacy of Dapiprazole in the Reversal of 5% Phenylephrine/0.5% Tropicamide Induced Mydriasis

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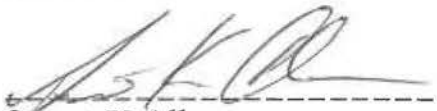
SIGNATURES

Authors:



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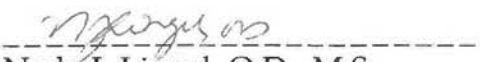

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The Effects of Dapiprazole on the Reversal of 5% Phenylephrine/0.5% Tropicamide Induced Mydriasis

Introduction

Pupillary dilation to allow fundus examination is an integral part of the comprehensive vision exam. Binocular Indirect Ophthalmoscopy (BIO) and high plus ophthalmoscopy allow a more comprehensive assessment of the posterior pole and peripheral fundus. Because of the increased illumination necessary to perform the previously mentioned techniques, diagnostic pharmaceutical agents are needed to provide and maintain adequate pupil size. The standard protocol involves the instillation of two consecutive drops at 5 minute intervals. Typically, these drops include one each of phenylephrine 2.5% and tropicamide 1.0%. Phenylephrine, a sympathomimetic, contracts the iris dilator muscle and tropicamide, a parasympatholytic, relaxes the iris sphincter muscle. The combined effects of these agents inhibit the efferent pupillary light reflex. Many practitioners and patients find this pupillary dilation process both time consuming and bothersome. A previous attempt to resolve this problem was made with the introduction of the combination mydriatic solution Paremyd which contains 1.0% hydroxyamphetamine and .25% tropicamide. However, there is a general feeling among clinicians that Paremyd does not provide an adequate maximum pupillary dilation.

It has been proposed that a mydriatic solution containing a combination of 5% phenylephrine and 0.5% tropicamide would reduce the time and inconvenience of the standard protocol by lowering the number of consecutive drops from two to one and at the same time achieve a satisfactory maximum pupillary dilation. Studies have already been conducted as to the onset, peak, and duration of dilation of this mydriatic solution. The purpose of this study is to evaluate the efficacy of dapiprazole (Rev-Eyes™), an a-adrenergic antagonist, in the reversal of mydriasis induced with this proposed solution.

The reversal effects of α–adrenergic antagonists of mydriasis caused by the standard dilating agents Tropicamide 1% and phenylephrine 2.5% is well documented. This reversal is typically complete in approximately one hour. In this study, the efficacy of dapiprazole HCl 0.5% (Rev-Eyes™) in reversing the mydriasis induced by 5% phenylephrine and 0.5% tropicamide was compared to the

efficacy of Rev-Eyes™ in reversing the mydriasis induced by the standard 1% tropicamide and 2.5% phenylephrine.

Dapiprazole HCl is an α–adrenergic antagonist that produced miosis and slightly reduces IOP following instillation in the eye. Dapiprazole exerts its action on the α-receptors of the iris dilator muscle. Through competitive inhibition, it occupies these receptors and prevents their further stimulation by α-receptors agonists such as phenylepherine.

Relative to the number of drops each patient received and the concentrations of drug contained in each drop, we hypothesize that Rev-Eyes™ will reverse the mydriasis caused by 5% phenylephrine and 0.5% tropicamide at least as fast as the mydriasis caused by the standard tropicamide 1% and phenylephrine 2.5%.

Materials and Methods

This study involved the use of ten subjects, all students at PUCO. Each were evaluated prior to the study using the Von Herrick method of angle estimation to ensure open angles. This method was used to evaluate the nasal and temporal angles in each subject to reduce the likelihood of angle closure. Goldmann Applanation Tonometry was performed one day prior to the experiment. Pressures were taken to ensure IOP was within normal limits and to reduce the possibility of the anesthetic altering the absorption of the mydriatic drops.
Iris color was noted prior to the study as well. Blood pressure was taken prior to the study to ensure all the subjects were within normal limits for their respective age groups.

Pre-requisites for participation in the study included no ocular pathology and best corrected visual acuity of 20/20 OU or better.
The study performed was double blind -- neither the experimenters or the subjects knew which drops were being used on any of the subjects.
The study was performed on two consecutive Saturdays
The initial Saturday one half the test group received the standard dilating agents and the other half received one drop of the experimental solution. Baseline pupil diameters were measured prior to instillation of the drops. Pupil diameters were measured until maximum dilation was achieved. At that time, Rev-Eyes™ was instilled as in a manner consistent with the package insert (two drops in each eye, followed by two more drops five minutes later). At that point pupil diameter was measured every five minutes for 30 minutes for a total of 6 measurements, then every 15 minutes for one hour (4 times) then every half hour for one hour (2 times)

Measurements were taken with the Shinn-Nippon digital PD-82 Pupillometer. Inter-examiner variability was avoided in all measurements by having the same examiner take measurements on all subjects. Pupils were measured with the pupillometer to the nearest 0.5mm in the horizontal meridian. This was done by setting the pupillometer to the infinity setting. Monocular horizontal pupil measurements were taken by aligning the vernier with the temporal edge of the pupil, obtaining a reading, aligning the vernier with the nasal edge of the pupil and obtaining another reading. The difference between the two readings was the pupil diameter. The procedure was then repeated for the other eye. The following Saturday, the opposite drop was given to each subject and the measurements were repeated in the same manner.

Results

After the data was collected, it was then analyzed using the statistical hog-wash to allow us to compare and contrast the reversal characteristics relative to each mydriatic drop. Is it at least as effective???